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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,321	07/28/2003	David Delancy	SKEL-007	6585
24353 7590 05/18/2007 BOZICEVIC, FIELD & FRANCIS LLP 1900 UNIVERSITY AVENUE SUITE 200 EAST PALO ALTO, CA 94303			EXAMINER JONES, DAMERON LEVEST	
			ART UNIT 1618	PAPER NUMBER
			MAIL DATE 05/18/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/629,321

Applicant(s)

DELANEY ET AL.

Examiner

D. L. Jones

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/7/07 & 2/2/07.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 and 25-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 and 25-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1618

ACKNOWLEDGMENTS

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/7/07 has been entered.

2. The Examiner acknowledges receipt of the amendment filed 2/2/07 wherein claims 1, 25, and 26 are amended and claim 24 is canceled.

Note: Claims 1-23 and 25-30 are pending.

RESPONSE TO APPLICANT'S AMENDMENT/ARGUMENTS

3. The Applicant's arguments and/or amendment filed 2/2/07 to the rejection of the claims made by the Examiner under 35 USC 103 have been fully considered and deemed persuasive. Therefore, the said rejection is hereby withdrawn.

NEW GROUNDS OF REJECTIONS

112 Rejections

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1618

5. Claims 1-23 and 25-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-9, 11-14, and 23: The claims as written are ambiguous because one cannot ascertain what is being claimed in independent claim 1. In particular, in lines 7-8 of independent claim 1, it is disclosed that the water soluble contrast agent is incorporated into the calcium phosphate product 'in a ratio sufficient to produce said flowable material'. This phrase is vague and indefinite because it is unclear what ratio Applicant is referring to that is encompassed by the instant invention. Review of Applicant's specification indicates that the ratio of the setting fluid and the water soluble contrast agent is such that the liquids to solids ratio employed typically ranges from about 0.2 to 1.0 (see Applicant's published application, US 2005/0023171, paragraph [0027]). Thus, what appears in the specification indicates at what ratio Applicant's product is flowable, while the claim is ambiguous. Applicant is respectfully requested to amend the claim to set forth the ratio at which the product is flowable. Furthermore, it should be noted that since independent claim 1 is vague and indefinite all claims depending thereupon are also vague and indefinite.

Claims 1-14: The claims as written are ambiguous because it is unclear what conditions are necessary to determine that the flowable material comprises 'poorly; crystalline calcium phosphate mineral. Specifically, the term "poorly" in independent claim 1 is a relative term which renders the claim indefinite. The term "poorly" is not defined by the claim, the specification does not provide a standard for ascertaining the

Art Unit: 1618

requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Likewise, the same is held true for claims 25-30. Thus, those claims are also ambiguous.

Claims 15-22: The claims as written are ambiguous because one cannot ascertain what is being claimed in independent claim 15. In particular, in lines 7-8 of independent claim 1, it is disclosed that the water soluble contrast agent is incorporated into the calcium phosphate product 'in a ratio sufficient to produce said flowable material'. This phrase is vague and indefinite because it is unclear what ratio Applicant is referring to that is encompassed by the instant invention. Review of Applicant's specification indicates that the ratio of the setting fluid and the water soluble contrast agent is such that the liquids to solids ratio employed typically ranges from about 0.2 to 1.0 (see Applicant's published application, US 2005/0023171, paragraph [0027]). Thus, what appears in the specification indicates at what ratio Applicant's product is flowable, while the claim is ambiguous. Applicant is respectfully requested to amend the claim to set forth the ratio at which the product is flowable. Furthermore, it should be noted that since independent claim 15 is vague and indefinite all claims depending thereupon are also vague and indefinite.

Claims 15-20 and 22: The claims as written are ambiguous because it is unclear what time frame Applicant is referring to by the phrase 'a sufficient period of time to product a paste'.

COMMENTS/NOTES

6. The above action is deemed necessary in order to clarify the instant invention.

However, it should be noted that no prior art has been cited against the instant invention. In particular, the claims are distinguished over the prior art of record because the prior art neither anticipates nor renders obvious a product or method thereof comprising a calcium phosphate containing product having the limitations set forth in the instant invention. Furthermore, it should be noted that the closest art is Applicant's own work, US Patent Nos. 6,719,993 and 6,375,935, which are also directed to contrast agents. However, the patented inventions differ from the instant invention in that they do not suggest the incorporation of a water soluble radio opaque as in the instant invention.

7. The following comments are respectfully made in regards to the pending claims.


(1) Claim 5 does not further limit the invention because independent claim 1 has been amended to indicate that the radio opaque element is not calcium. Thus, it is respectfully suggested that the claim be canceled. (2) Applicant is reminded that the recitation that an element is 'capable of' performing a function is not a positive limitation, but only requires the ability to so perform that function. Thus, such terminology does not constitute a limitation in any patentable sense (In re Hutchison, 69 USPQ 138). Hence, it is respectfully suggested that Applicant replace the phrase 'capable of setting' with 'that sets' in column 15, line 10.

Due to the fact that it is the Examiner's position that some of the 112 rejections need to be addressed in writing, a telephone call was not made to Applicant to make the changes over the telephone.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


D. L. Jones
Primary Examiner
Art Unit 1618

May 11, 2007